

**BLUEFIELD REGIONAL
MEDICAL CENTER**
Touching Lives With Technology

October 27, 1989

U.S. Nuclear Regulatory Commission
Attn: Director, Office of Enforcement
Document Control Desk
Washington, D.C. 20555

Gentlemen:

RE: Reply to Notice of Violation (NRC Inspection Report Nos. 47-19142-01/89-01 and 47-19142-02/89-01) dated September 14, 1989.

As required in the above noted correspondence, we are submitting this as our response and corrective plan of action:

I. Violations of License No. 47-19142-01

- A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on June 14, 1989, licensed material consisting of cesium-137 brachytherapy sources and a strontium-90 calibration source stored in the teletherapy treatment room, an unrestricted area, was not secured against unauthorized removal, in that, neither the vault containing the sources nor the door to the teletherapy treatment room was locked and access to the area was not controlled outside normal Oncology Department working hours.

Response:

- 1) Violation is valid.
- 2) Recent construction removed a wall, which was previously in place, and which maintained a secured environment outside normal department operating hours.

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- 3) A padlock was installed on the Cobalt Therapy door.
 - 4) The Cobalt Therapy door will be locked during non-routine operational hours.
 - 5) Lock was installed June 20, 1989.
- B. 10 CFR 20.203(e) requires that each area or room in which licensed material is used or stored and which contains any radioactive material (other than natural uranium or thorium) in an amount exceeding ten times the quantity of such material specified in Appendix C of Part 20, be conspicuously posted with a sign or signs bearing the radiation symbol and the words "Caution - Radioactive Material(s)."

Contrary to the above, on June 14, 1989, two doors which accessed the Nuclear Medicine Department, where licensed material consisting of iodine-131 and technetium-99m radiopharmaceuticals exceeding ten times the quantities specified in Appendix C are used for diagnostic imaging and quantitative studies, were not conspicuously posted with "Caution - Radioactive Material" signs.

Response:

- 1) Violation is valid.
 - 2) Non-conforming signs previously approved during NRC inspections were present during this inspection.
 - 3) Conforming signs were placed in areas as required by regulations.
 - 4) Caution signs will be reviewed for compliance with current regulations.
 - 5) Conforming signs have been installed on June 20, 1989.
- C. 10 CFR 35.51(d)(1) and (2) require each survey instrument calibration record to include among other things the certified exposure rates from the source, the rates indicated by the instrument being calibrated, and a description of the calibration procedure.

Contrary to the above, between April 1, 1987 and June 14, 1989, the survey instrument calibration records did not contain the certified exposure rates from the source, the rates indicated by the instrument being calibrated, nor a description of the calibration procedure.

Response:

- 1) Violation is valid.

- 2) Violation occurred due to misinterpretation of NRC Regulations.
- 3) Instrument survey records now show the certified exposure rates from the source, the rates indicated by the instrument being calibrated and a description of the calibration procedure.
- 4) Calibration records will be maintained in accordance with current NRC Regulations.
- 5) Calibration survey procedure was revised September 20, 1989.

- D. 10 CFR 30.51(a) requires that each licensee keep records showing the receipt, transfer, and disposal of licensed byproduct material.

Contrary to the above, between April 16, 1986 and June 14, 1989, the required records, showing the receipt and transfer of byproduct material consisting of a strontium-90 therapeutic eye applicator were not kept.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to failure to maintain required transfer/receipt records for Strontium-90 therapeutic eye application.
- 3) Required documentation is now kept.
- 4) Documentation regarding source transfer will be reviewed as part of NRC compliance reviews.
- 5) Date of full compliance was June 20, 1989.

- E. 10 CFR 35.205(c) and (d) require that before receiving, using, or storing a radioactive gas, the amount of time needed after a spill to reduce the concentration in the room to the limit listed in 10 CFR Part 20, Appendix B be calculated, that a record of these calculations be made, and that the calculated time, and safety measures to be instituted in case of a spill be posted at the area of use.

Contrary to the above, between April 1, 1987 and June 14, 1989, the licensee failed to post the calculated time and safety measures to be instituted in case of Xenon-133 radioactive gas spill in the Nuclear Medicine Department.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to failure to post information as required by NRC Regulations.

- 3) Calculated time and safety measures to be instituted in case of Xenon-133 radioactive gas spill are now posted in the nuclear medicine department.
- 4) Future reviews for compliance with NRC Regulations will include review for required posted documentation.
- 5) Date of full compliance was June 20, 1989

- F. 10 CFR 35.51(c) requires that each survey instrument be checked for proper operation with a dedicated check source each day of use. 10 CFR 35.5(a)(3) requires that the apparent exposure rate from dedicated check source as determined at the time of calibration be conspicuously noted on the survey instrument.

Contrary to the above, checks with a dedicated check source performed for proper operations of each survey meter, each day of use between April 1, 1987 and June 14, 1989 were inadequate, in that the nuclear medicine technologist failed to compare the exposure rate obtained with the dedicated check source with the apparent exposures rates from the source as determined at the time of instrument calibration which was conspicuously noted on the survey instrument.

Response:

- 1) Violation is valid.
 - 2) This violation occurred due to technologists not being familiar with current instrument survey regulations.
 - 3) An inservice has been provided to identify and implement current procedure required by NRC Regulations.
 - 4) Reviews to verify compliance with NRC Regulations will include reviewing instrument survey procedures.
 - 5) Date of compliance was September 20, 1989.
- G. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their plants or deliver licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170 through 189.

49 CFR 173.415(a) requires each shipper of a specification 7A package to maintain on file for at least one year after the latest shipment a complete documentation of tests and an engineering evaluation or comparative data showing that the construction methods,

packaging design, and materials of construction comply with that specification.

Contrary to the above, on June 14, 1989, documentation of the appropriate tests for a specification 7A package was not maintained on file for the molybdenum-99/technetium-99m generator packages shipped between June 14, 1988 and June 14, 1989.

Response:

- 1) Violation is not valid.
- 2) The documentation for appropriate tests for specification 7A packages was present in the department during the inspection and was presented at the Enforcement Hearing in Atlanta, GA on July 27, 1989.
- 3) We believe no corrective action steps are required.
- 4) No further corrective steps are necessary.
- 5) We believe we are currently in compliance with NRC Regulations.

- H. License Condition 8.B limits the amount of each byproduct material authorized in Subitem 6.B. that may be possessed at any one time to no more than three curies. Subitem 6.b. permits the licensee to possess molybdenum-99/technetium-99m generators listed in 10 CFR 35 Schedule A, Group III, the revision of 10 CFR 35 in effect when the license was issued.

Contrary to the above, on May 27, 1989, the possession limit authorized by the license was exceeded, in that, at approximately 6:00 a.m., the licensee received a molybdenum-99/technetium-99m generator containing an amount greater than three curies. Specifically, the generator was assayed by the supplier to be three curies on May 29, 1989, at 8:00 p.m.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to acceptance of generator that contained material that exceeded condition of license limits.
- 3) Receipt forms have been modified to require notification of supplier in accordance with current NRC Regulations.
- 4) Future reviews for NRC compliance will include review of receipt policies and procedures.
- 5) Date of compliance was July 5, 1989.

- I. License Condition 20 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application dated September 6, 1979, letter dated October 29, 1979; Model ALARA program contained in Appendix D of Regulatory Guide 10.8 (Rev. 1), October 1980; letter dated May 26, 1981; application dated February 16, 1983; and letters dated February 23, 1983, November 3, 1983, and October 1, 1984.

1. Item 9 of the letter dated October 29, 1979, requires that the xenon trap system be surveyed on a weekly frequency in order to ensure that the filter has not become saturated.

Contrary to the above, between April 16, 1986 and May 2, 1989, surveys of the xenon trap were performed on a monthly rather than on a weekly frequency.

Response:

- 1) Violation is valid.
 - 2) Violation occurred due to non-compliance with current license requirements.
 - 3) Xenon trap surveys will be conducted in compliance with current license requirements.
 - 4) Future program reviews will be conducted to review compliance with NRC Regulations as well as current license conditions.
 - 5) Date of compliance July 24, 1989.
2. Item 14, Procedures B.3 and 4 of the application dated September 6, 1979, require that unopened packages containing radioactive material be monitored with a survey meter; that the package not be opened if the radiation level exceeds 200 mR per hour at the surface, or 10 mR per hour at three feet; and that if the radiation levels are exceeded, the radiation safety officer or health physics consultant and chief of the department be notified for further instruction. The radiation safety officer or consultant shall notify the appropriate officials of the Nuclear Regulatory Commission or State Health Department, the final delivery carrier, and the vendor.

Contrary to the above, packages containing radioactive material received on May 8 and September 8, 1988, February 22, March 1 and May 27, 1989, which had radiation levels between 12 and 35 mR/hr at 3 feet from the surface of the unopened package as monitored by a survey meter,

were opened and the required notifications were not made.

Response:

- 1) This violation is valid.
- 2) This violation occurred due to not following conditions of current license.
- 3) Receipt forms have been revised to comply with current license requirements and NRC Regulations.
- 4) Future program reviews will include review for compliance with current license conditions as well as NRC Regulations.
- 5) Date of compliance was June 16, 1989.

3. Item 14, Procedure B.8, of the application dated September 6, 1979, requires, in part, that the packing material and empty packages, used for shipping radioactive material, be monitored for contamination before discarding in either the radioactive or regular trash.

Contrary to the above, between April 16, 1986 and June 14, 1989, packing material and empty packages, used for shipping radioactive iodine-131 and xenon-133, were not monitored for contamination before discarding into the hospital's trash.

Response:

- 1) Violation is valid.
- 2) This violation occurred due to failure to comply with conditions of current license.
- 3) Receipt forms for packages have been revised to include survey of packing materials as well as the actual package.
- 4) Future program reviews will include monitoring for compliance with current license conditions as well as NRC Regulations.
- 5) Compliance date was June 20, 1989.

4. Item 10, Procedure 3, of the application dated September 6, 1979, requires that survey meters be calibrated on a quarterly basis.

Contrary to the above, between August 22, 1986 and June 14, 1989, two survey meters (Eberline E 120, Serial No. 7522 and Eberline E-130G, Serial No. 6919) were not calibrated on a quarterly basis. Additionally, between August 21, 1987 and June 14, 1989, another survey meter (Bicron Surveyor 2000,

Serial No. A230K) was not calibrated on a quarterly basis.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to failure to comply with conditions of license.
- 3) Survey meters will be calibrated as required in the current NRC license application and in compliance with NRC Regulations.
- 4) Future program reviews will assess for compliance in accordance with current license conditions.
- 5) Date of full compliance was July 5, 1989.

5. Item 20 of the application dated February 16, 1983, requires that procedures described in Appendix L of Regulatory Guide 10.8, Revision 1, October 1980 be followed.

Item 6. of Appendix L requires that nurses caring for brachytherapy patients be assigned film or TLD badges and that TLD finger badges also be assigned to nurses who must provide extended personal care to the patient.

Contrary to the above, between April 16, 1986 and June 14, 1989, neither film or TLD badges nor TLD finger badges were assigned to nursing personnel who either cared for brachytherapy patients or provided extended personal care for brachytherapy patients undergoing therapeutic applications using cesium-137.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to failure to comply with conditions of current license.
- 3) Policy for monitoring of nurses caring for brachytherapy patients has been revised and implemented and is in compliance with current license conditions and NRC Regulations.
- 4) Program reviews will be utilized to ensure that compliance is maintained.
- 5) Date of full compliance was August 2, 1989.

6. Item 12. of the application dated September 6, 1979, requires that in addition to on-the-job training, all individuals who work with radioactive sources receive periodic training at least annually in radiation safety. The training

subjects shall include, but not limited to, radiological safety procedures described in the license.

Contrary to the above, between April 16, 1986 and June 14, 1989, Nuclear Medicine Technologists, individuals who work with radioactive sources, did not receive the periodic training at least annually in radiation safety which included the radiological safety procedures described in the license.

Response:

- 1) Violation is not valid.
 - 3) No corrective action is believed necessary at this time.
 - 4) Inspectors asked if RSO provided all training and inservice and the staff technologists indicated that he did not. These types of inservices and educational programs are provided by our physics consultant and are recorded and documented according to NRC Regulations and were present and available in the department at the time of NRC survey.
 - 5) Date of full compliance non-applicable.
7. Item 12. of the application dated February 16, 1983, requires that an inventory of all brachytherapy sources be performed at least monthly.

Contrary to the above, between April 16, 1986 and June 14, 1989, an inventory of all brachytherapy sources was not performed at least monthly.

Response:

- 1) Violation is valid.
 - 2) Violation occurred due to failure to comply with current license conditions.
 - 3) Policy and procedure for conducting inventories of all brachytherapy sources has been revised to maintain inventories as required by conditions established by the current license.
 - 4) Future program reviews will be conducted to ensure compliance with current license conditions and NRC Regulations.
 - 5) Date of full compliance was July 5, 1989.
8. 10 CFR 35.14(f)(2) (effective up to April 1, 1987) requires that a quarterly physical inventory be conducted to account for all sources received and

possessed.

Contrary to the above, a quarterly physical inventory of a cesium-137 reference source (NEN, Cat. NES-356, #3560584A-30) and cobalt-60 reference source (NEN, Cat. NES-354, #3540584A-04) was not performed between February 4, 1986 and July 1, 1986; and between July 1, 1986 and January 13, 1987.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to failure to comply with current NRC Regulations.
- 3) Policy and procedure has been revised to reflect changes in NRC Regulations requiring physical inventories on a quarterly basis for all sources received and in possession.
- 4) Future program reviews will be conducted to ensure compliance with all current and new NRC Regulations.
- 5) Date of full compliance was July 5, 1989.

II. Violations of License No. 47-19142-02

License Condition 22 requires that the licensee conduct its program in accordance with statements, representations, and procedures contained in the application dated March 13, 1986, and letter with attachments received September 3, 1986.

1. Attachment 2, Item 15, of the letter with attachments received September 3, 1986, requires that practice drills of the teletherapy emergency procedures be performed at least once a year with all appropriate personnel. New personnel shall perform practice drills as soon as these individuals report for duty.

Contrary to the above, between November 2, 1986 and September 29, 1988, teletherapy emergency practice drills were not performed at least annually with all appropriate personnel.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to failure to comply with conditions of current license.
- 3) Current policy and procedure contains provisions for conducting a teletherapy emergency practice drill on an annual basis and also for orienting new personnel in the area to this aspect of the operation.

- 4) Future program reviews will ensure compliance with this condition of license and other NRC Regulations relating to this issue.
 - 5) Date of full compliance was July 5, 1989.
2. Attachment 4 of the letter with attachments received September 3, 1986, requires that the items listed below be checked and logged in the appropriate records weekly.
- a) teletherapy timer
 - b) beam "on" and "off" lights on the console, machine head, and above the door
 - c) emergency switches
 - d) door interlocks
 - e) beam collimators using radiographic film and a densitometer
 - f) two independent TV monitor systems

Contrary to the above, between May 13 and June 16, 1988, and between July 15 and 29, 1988, the teletherapy timer, beam "on" and "off" lights, emergency switches, door interlocks and two independent TV monitor systems were not checked weekly. Additionally, between April 7 and May 5, 1987, between May 5 and June 2, 1987, and between June 2 and July 3, 1987, such checks were not logged in the appropriate records. Further, between June 14, 1987 and June 14, 1989, the beam collimators were not checked using radiographic film and a densitometer on a weekly frequency.

Response:

- 1) Violation is valid.
 - 2) Violation occurred due to failure to comply with condition of current license.
 - 3) Policies and procedures to perform checks as outlined are in place and were not adhered to during stated periods of time due to rapid personnel turnover.
 - 4) Future program reviews will include reviews to ensure that checks be completed and logged in compliance with current license requirements and NRC Regulations.
3. Attachment 2, Item 3, of the letter with attachments received September 3, 1986, requires that daily checks of the teletherapy beam-on monitor and survey instrument be performed.

Contrary to the above, between May 13 and June 16, 1988 and between July 15 and 29, 1988, daily checks of the beam-on monitor and survey instrument were not

performed.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to failure to comply with current license conditions.
- 3) Policies and procedures are currently in place to provide monitoring and checks but were not completed during the stated time periods due to rapid personnel turnover and administrative oversight.
- 4) Future program reviews will ensure that all monitoring and checks are completed in accordance with current license conditions and NRC Regulations.
- 5) Date of full compliance is July 5, 1989.

In addition to the corrective actions listed above, we will use suggested guidelines for audit procedures provided by the NRC. Until the guidelines are provided by the NRC, we will use the following guidelines and procedures to ensure compliance:

1. We will propose a Medical Staff ByLaws revision that will make the Radiation Safety Committee a committee of the medical center rather than one of the medical staff and we will conform with current ALARA guidelines.
2. The Chairman of the Radiation Safety Committee will not be a Radiation Safety Officer or assistant officer.
3. A centralized information center within the department will be developed. Information kept in this area will include, but not be limited to: a copy of the current license including all pertinent revisions and amendments; a copy of current NRC Regulations including all pertinent revisions and updates; copies of all NRC correspondences relating to the operation and/or maintenance of the area; and all other pertinent policies and procedures, documentation and correspondences that are necessary for effective operation of the programs.
4. The Radiation Safety Officer shall be the primary auditor of policy and practice. The Radiation Safety Officer and/or his designee will perform routine review functions as well as periodic spot checks of specific NRC Regulations and/or license conditions. The RSO has been delegated authority by management and the RSC to take immediate corrective action involving by product materials that in his/her opinion represents a significant radiation hazard to the public or radiation occupational workers. Management and the RSC will be advised as soon as possible. Discrepancies deemed less serious by the Radiation Safety Officer will be discussed

with the Chairman, Radiation Safety Committee and managed as deemed necessary. Corrective action will be instituted, unless in the judgement of these individuals, a formal meeting of the Radiation Safety Committee is necessary.

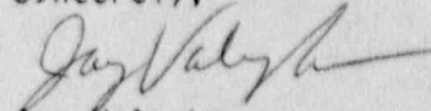
5. A summary of actions related to the Radiation Safety Program will be presented to the Radiation Safety Committee by the Radiation Safety Officer at the regularly scheduled Committee Meetings.
6. A management report will be presented at the regularly scheduled Radiation Safety Committee meetings and will include information relating to issues such as construction, renovation, equipment replacement, repairs and maintenance. A strong emphasis will be placed on safety compliance issues including education and training.

Our efforts are intended to provide effective management review and along with our planned internal review mechanisms, to provide a framework to ensure compliance with NRC Regulations and our current license conditions.

We believe that the actions that we have listed above, along with the corrective actions that we presented at our enforcement conference held in July, 1989 will meet all requirements for compliance with our NRC license.

If any additional information is required or if we can answer any questions please feel free to contact us at your convenience.

Sincerely,


Jay Valeyko
Administrator

cc: Stewart D. Ebnetter, Regional Administrator